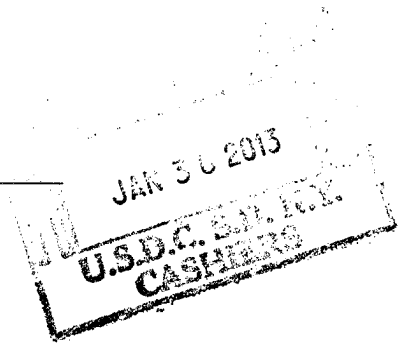
13 CV 0684

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES, Plaintiffs, v. IMPAX LABORATORIES, INC., Defendant.	)	C.A. No. _____



COMPLAINT

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies for their Complaint herein, aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

THE PARTIES: PLAINTIFFS

2. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431. Purdue Pharma is an owner of United States Patent Nos. 7,674,799, 7,674,800, and 7,683,072 identified in paragraphs 12-14 below. Purdue Pharma is also the holder of New Drug Application ("NDA") No. 020553 for the controlled-release oxycodone pain-relief medication OxyContin®, and is involved in the sales of OxyContin® in the United States.

3. Plaintiff The P.F. Laboratories, Inc. ("P.F. Labs") is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 700 Union Boulevard, Totowa, NJ 07512. P.F. Labs is an owner of United States Patent Nos. 7,674,799, 7,674,800, and 7,683,072 identified in paragraphs 12-14 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

4. Plaintiff Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner of United States Patent Nos. 7,674,799, 7,674,800, and 7,683,072 identified in paragraphs 12-14 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

5. Plaintiff Rhodes Technologies ("Rhodes") is a general partnership organized and existing under the laws of the State of Delaware, having a place of business at 498 Washington Street, Coventry, RI 02816. Rhodes is an owner of United States Patent Nos. 7,674,799, 7,674,800, and 7,683,072 identified in paragraphs 12-14 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

6. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are associated companies.

THE PARTIES: DEFENDANT

7. Upon information and belief, Defendant Impax Laboratories, Inc. ("Impax") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 30831 Huntwood Avenue, Hayward, CA 94544.

8. Upon information and belief, Impax is registered as a Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions. (Registration No. 025847). The Registration has an active status.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

10. This Court has personal jurisdiction over Impax because, *inter alia*, Impax has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Impax does business in this State and this Judicial District, has engaged in continuous and systematic contact with this State and this Judicial District, and derives substantial revenue from things used or consumed in this State and this Judicial District. Upon information and belief, Impax engages in the manufacture and sale of a range of pharmaceutical products within and directed to the United States and this Judicial District specifically. Impax did not contest personal jurisdiction in this Judicial District in patent litigation concerning United States Patent Nos. 7,674,799, 7,674,800, and 7,683,072, which suit was based on another Abbreviated New Drug Application ("ANDA") that Impax submitted to the FDA based on Purdue Pharma's OxyContin® NDA No. 022272. *See Purdue Pharma L.P. et al. v. Impax Laboratories, Inc.*, No. 11-civ-2400 (SHS) (S.D.N.Y. Apr. 7, 2011). Further, this Court has personal jurisdiction over Impax because, upon information and belief, Impax has an active registration status in the Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions. In addition, upon information and belief, Impax is actively preparing to make the proposed generic copies of OxyContin® that are the subject of ANDA Nos. 76-446 and 76-318, and to use, sell and offer for sale such generic copies in this State and this Judicial District.

11. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENTS IN SUIT

12. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,674,799 entitled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE" ("the '799 patent"), including all right to sue and to recover for past infringement thereof, which patent is listed in FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 020553. A copy of the '799 patent is attached hereto as Exhibit A, which was duly and legally issued on March 9, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

13. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,674,800 entitled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE" ("the '800 patent"), including all right to sue and to recover for past infringement thereof, which patent is listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 020553. A copy of the '800 patent is attached hereto as Exhibit B, which was duly and legally issued on March 9, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

14. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,683,072 entitled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE" ("the '072 patent"), including all right to sue and to recover for past infringement thereof, which patent is listed in the FDA's Orange Book as covering the drug

OxyContin®, which is the subject of approved NDA No. 020553. A copy of the '072 patent is attached hereto as Exhibit C, which was duly and legally issued on March 23, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

DEFENDANT'S ANDA NO. 76-446

15. Upon information and belief, Impax submitted ANDA No. 76-446 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of generic oxycodone hydrochloride extended release tablets, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg ("proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg"), based on the Reference Listed Drug ("RLD") OxyContin®, which is the subject of approved NDA No. 020553, before the expiration of the '799, '800, and '072 patents.

16. Upon information and belief, Impax's ANDA No. 76-446 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '799, '800, and '072 patents, listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 020553, are "invalid, unenforceable, or not infringed" by the commercial manufacture, use, sale, offer for sale, or importation of its proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg.

17. In a letter dated December 14, 2012 addressed to Plaintiffs and received by Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes on December 17, 2012, Impax provided "Notice" with respect to its proposed generic copies of OxyContin® and the '799, '800, and '072 patents under 21 U.S.C. § 355(j)(2)(B).

DEFENDANT'S ANDA NO. 76-318

18. Upon information and belief, Impax submitted ANDA No. 76-318 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking

approval to engage in the commercial manufacture, use, sale, offer for sale or importation of generic oxycodone hydrochloride extended release tablets, 60 mg and 80 mg ("proposed generic copies of OxyContin®, 60 mg and 80 mg"), based on the RLD OxyContin®, which is the subject of approved NDA No. 020553, before the expiration of the '799, '800, and '072 patents.

19. Upon information and belief, Impax's ANDA No. 76-318 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '799, '800, and '072 patents, listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 020553, are "invalid, unenforceable, or not infringed" by the commercial manufacture, use, sale, offer for sale, or importation of its proposed generic copies of OxyContin®, 60 mg and 80 mg.

20. In a letter dated December 14, 2012 addressed to Plaintiffs and received by Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes on December 17, 2012, Impax provided "Notice" with respect to its proposed generic copies of OxyContin® and the '799, '800, and '072 patents under 21 U.S.C. § 355(j)(2)(B).

CLAIM FOR RELIEF

21. Impax's submission of its ANDA No. 76-446 and ANDA No. 76-318 was an act of infringement of the '799, '800, and '072 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

22. Upon information and belief, Impax's proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, are covered by one or more claims of the '799, '800, and '072 patents.

23. Upon information and belief, Impax's commercial manufacture, use, sale, and/or offer for sale of its proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg,

40 mg, 60 mg, and 80 mg, would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '799, '800, and '072 patents.

24. Upon information and belief, Impax has been aware of the existence of the '799, '800, and '072 patents, and has no reasonable basis for believing that its proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, will not infringe the '799, '800, and '072 patents, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

25. The acts of infringement by Impax set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

WHEREFORE, Plaintiffs pray for judgment:

A. Adjudging that Impax has infringed the ' 799, '800, and '072 patents, and that the commercial sale, offer for sale, use, and/or manufacture of its proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, described in ANDA No. 76-446 and its proposed generic copies of OxyContin®, 60 mg and 80 mg, described in ANDA No. 76-318 would infringe, induce infringement of, and/or contribute to the infringement of the '799, '800, and '072 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 76-446 and ANDA No. 76318, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the dates of expiration of the '799, '800, and '072 patents plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Impax, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities

and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that infringes the '799, '800, and '072 patents;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

Dated: January 30, 2013

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